DETAILED ACTION

Election/Restrictions

1.   Applicant's election without traverse of Group I in the reply filed on August 22, 2011 is

acknowledged.

2.   Applicant's election of the species of claim 32 is acknowledged. The examiner further

acknowledges that claims 32, 33, 6 and 7 are not mutually exclusive and that claim 8 is generic

to claim 7 and so therefore have examined claims 6-8, 32 and 33. New claim 48 however

introduces another species and would have been listed with the previously listed species had it

been previously claimed. Since the applicant elected the species of claim 32 claim 48 is

withdrawn along with claim 9 from further consideration pursuant to 37 CFR 1.142(b), as being

drawn to a nonelected species, there being no allowable generic or linking claim. Applicant

timely traversed the restriction (election) requirement in the reply filed on August 22, 2011.

Claim Objections

3.   **Claims 5 and 24-26** recites the limitation "the section of tissue". There is insufficient

antecedent basis for this limitation in the claim. Suggested correction is --the tissue--.

4.   **Claim 48** recites the limitation "the melanin content". There is insufficient antecedent

basis for this limitation. Suggested correction is --a melanin content--.

Claim Rejections - 35 USC § 112

5.   The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6.   **Claims 6-9, 32, 33, and 48** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide a way to use and make the invention so that the features of the Raman spectrum collected of a Raman shift relative to a wavelength of incident light is within a particular band range (such as in the ranges of about 1200 cm^{-1} to about 1400 cm^{-1} or about 1500 cm^{-1} to about 1650 cm^{-1}) or at a particular peak (such as at 1445 cm^{-1}, at 1269 cm^{-1}, at 1368 cm^{-1}, or at 1572 cm^{-1}). These peaks and band ranges depend upon the molecules present in the measured tissue region of interest. The applicant does not appear to make the system or method have those particular peaks and ranges. It is suggested the applicant amend the claims towards the characterizing of tissue depends upon the peaks measured, and if a peak or range is discovered in a particular range then it is concluded that the tissue has a particular characterization.

Claim Rejections - 35 USC § 102

7.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8.   **Claim 1, 24-27, 29, 34, 40, and 49** are rejected under 35 U.S.C. 102(b) as being

anticipated by Gellermann (US 6,205,354 B1). Gellermann discloses a method and apparatus for

characterizing a tissue comprising directing a light source 12 (fig. 1) generating nearly

monochromatic light (col. 6 line 36-40) at a section of tissue such as the skin (epithelial tissue),

lung, or colon (gastrointestinal tract) (col. 5 line 6-8), collecting and directing backscattered light

into a spectrometer 26 (fig. 1) via an optical system 14 (fig. 1), and receiving, in a data processor

30 (fig. 1), raw spectrum information for the backscattered light which includes both features of

a Raman spectrum in a first wavelength range and features of a background fluorescence

spectrum, which is a background to the Raman spectrum in the first wavelength range, in a

second wavelength range overlapping with the first wavelength range (col. 5 line 61-67, col. 7

line 42-44). The data processor also characterizes the tissue based upon comparing the Raman

features and the background fluorescence features of the tissue to the Raman features and

background fluorescence features of a control area of normal tissue to assess the risk or presence

of a malignancy disease such as cancer (col. 6 line 21-31, col. 8 line 53-55).

Claim Rejections - 35 USC § 103

9.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

10.   **Claims 28, 30, and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gellermann. Gellermann discloses using the invention on biological tissue. It would have been

obvious to one skilled in the art to use the invention of Gellermann on an ear, nose or throat as these are well known biological tissues, for the purpose of detecting if a patient's ear, nose, or throat has any tissue abnormalities. Gellermann also discloses the invention used to determine the risk of skin cancer (col. 8 line 48-55) and discloses typical skin cancers include basal cell carcinoma, squamous cell carcinoma, and melanoma (col. 8 line 37-39) so it would therefore be obvious to screen for skin cancers such as basal cell carcinoma, squamous cell carcinoma, and melanoma.

11.   **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellermann further in view of Zeng (US 6,069,689). Zeng discloses other skin diseases besides basal cell carcinoma, squamous cell carcinoma is compound nevus (col. 4 line 53-col. 5 line 6). It would have been obvious to use the spectroscopic system of Gellermann to characterize compound nevus as it is well known in the art to use spectroscopic systems as disclosed by Zeng to characterize skin diseases besides basal cell carcinoma and squamous ell carcinoma to characterize compound nevus.

12.   **Claim 23** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellermann further in view of Tumer (US 6,135,965). Tumer discloses applying the spectral features into a neural network (abstract). It would have been obviosu to one skilled in the art at the time the invention was made to input the spectral features obtained from Gellermann into a neural network as taught by Tumer for the purpose of identifying spectra corresponding to abnormal tissues.

13.   Claims 2, 4-12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gellermann further in view of Alfano (US 5,293,872).

14.   **Claims 2, 4, 6-8:** Gellermann fails to explicitly disclose the first and second wavelength

ranges including wavelengths from about 800 to about 1000 nm, a wavelength range that

includes wavelengths in the near infrared. In the same field of endeavor of using Raman

spectroscopy to diagnose cancer or precancers Alfano discloses using wavelengths from about

800 nm to about 1000 nm (col. 4 line 59-line 61). It would have been obvious to one skilled in

the art at the time the invention was made to use a wavelength range of about 800-1000 nm as

disclosed by Alfano in Gellermann as Gellermann discloses that any wavelength of light could

be used if desired (col. 6 line 49-53) and because both Alfano and Gellermann discloses using a

Nd:YAG laser which emits in the infrared wavelengths (col. 4 line 66 of Alfano, col. 11 line 29

of Gellermann). Alfano further discloses presence of 1445 cm^{-1} and 1269 cm^{-1} (band of about

1200 cm^{-1} to 1400 cm^{-1}) peaks.

15.   **Claims 5, 10-12, 15:** Gellermann further discloses extracting the features of the Raman

spectrum (fig. 4) from the raw spectrum (fig. 3) by fitting a background fitting function to the

fluorescence background of the raw spectrum to yield a fitted background function and

subtracting the fitted background function from the raw spectrum (col. 10 line 42-46).

16.   Claims 17-21, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gellermann, as applied to claim 1 above, further in view of Richards-Kortum (US 5,991,653).

17.   Claims 16 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gellermann in view of Alfano as applied to claim 10 above, further in view of Richards-Kortum

(US 5,991,653).

18.   **Claims 16-21, 50, 51:** Gellermann discloses the claimed invention except for applying a

classification function derived from principal component analysis. In the same field of endeavor

of using Raman spectroscopy to diagnose cancer or precancers Richards-Kortum discloses

forming a set of principal components for normal tissue and various forms of abnormal tissue

and applying to a collected raw spectrum a classification function derived from one of the sets of

principal component analysis (col. 3 line 35-40, col. 7 line 20-col. 8 line 50). It would have been

obvious to add a principal component analysis as disclosed by Richards-Kortum to the raw

spectrum data of Gellermann for the purpose of condensing all the spectral information into a

few manageable components, with minimal information loss (col. 7 line 34-36 of Richards-

Kortum).

19.   **Claim 35:** Richards-Kortum discloses that NIR Raman spectroscopy has increased

penetration depth so it is obvious that the backscattered light is from light having passed through

overlying tissue (col. 6 line 52-59).

Conclusion

20.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-

5596. The examiner can normally be reached on M-F 10:00-6:30.

21.   If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Robert Chen can be reached on 571-272-3672. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

22.   Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Cheng/
Primary Examiner, Art Unit 3777